

Appln. No. 09/806,689
Amd. dated September 9, 2004
Reply to Office Action of April 9, 2004

REMARKS

The Office Action has been carefully reviewed. No claim is allowed. Claims 1-22 presently appear in this application, with claims 1-7, 18-20, and 22 being withdrawn from consideration by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 8-17 and 21 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is respectfully traversed.

Regarding the indefiniteness issue on what the comparison in step (x) (now amended to be step (vii)) in claim 8 (as well as for claims 9 and 13) on page 8, lines 5-7, means, the present specification discloses that:

Where necessary, the significance of the difference between the measured value and the cutoff value may be analysed by any of the known statistical tests such as, for example, Students' t-Test.

Furthermore, on page 11, lines 19-25, the present specification uses the term "significantly different" and again discloses that the significance of the difference will be determined by known statistical tests. Those of skill in the art would most definitely recognize when the difference is large that the difference is significant without even undertaking a statistical test. However, such a comparison can be assessed using statistical tests as taught in the specification, and thus it is not indefinite to those of skill in the art.

The remaining indefiniteness issues are obviated by the amendment to the claims.

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Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 8-17 and 21 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

Applicants respectfully disagree with the examiner's position here. Not only do applicants show the results from individuals with viral infection, e.g., HIV, in Fig. 11 and Example 4, but also from individuals with various kinds of infections including bacterial infections (sepsis).

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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